

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

UNITED STATES OF AMERICA; STATE OF)	
CALIFORNIA; STATE OF DELAWARE;)	
STATE OF FLORIDA; STATE OF HAWAII;)	
STATE OF ILLINOIS; STATE OF)	
MASSACHUSETTS; STATE OF NEVADA;)	
STATE OF TENNESSEE; STATE OF TEXAS;)	
STATE OF VIRGINIA; and DISTRICT OF)	Case No. 03 C 8239
COLUMBIA; ex rel. EDWARD WEST,)	
	Judge Virginia M. Kendall
Plaintiffs,)	
v.)	
)	
ORTHO-MCNEIL PHARMACEUTICAL, INC.)	
AND JOHNSON AND JOHNSON,)	
)	
Defendants.)	

MEMORANDUM OPINION AND ORDER

Plaintiff-Relator Edward West (“Relator” or “West”) brings this qui tam action on behalf of the United States under the False Claims Act (“FCA”), 31 U.S.C. §§ 3729-3732, and on behalf of California, Delaware, Florida, Hawaii, Massachusetts, Nevada, Tennessee, Texas, Virginia and the District of Columbia, under each state’s respective laws modeled after the FCA.¹ West alleges that Defendant Ortho-McNeil Pharmaceutical, Inc. (“Ortho-McNeil”) and its corporate parent, Defendant Johnson & Johnson knowingly caused to be presented false or fraudulent claims for payment and knowingly made false statements to get said governments to pay false or fraudulent claims. Defendants have moved to dismiss West’s First Amended Complaint for failure to plead with particularity, pursuant to Rule 9(b), and for failure to state a claim, pursuant to Rule 12(b)(6).

¹ A qui tam action is one that is brought by a private party (the “relator”) to assist the executive branch in its enforcement of the law; the Government remains the real party in interest. *See U.S. ex rel. Hall v. Tribal Development Corp.*, 49 F.3d 1208, 1212 (7th Cir. 1995).

Because West’s claims against Ortho-McNeil do not adequately set forth the “who, what, when, where and how” of the alleged fraud, they do not meet the pleading standard set forth in Rule 9(b). Additionally, West does not allege facts that plausibly suggest a claim against Johnson & Johnson either for its own conduct or the conduct of its subsidiary, Ortho-McNeil.

BACKGROUND

Ortho-McNeil is a pharmaceutical company and a wholly-owned subsidiary of Johnson & Johnson. (1st Am. Compl. ¶ 11.) West is a resident of Illinois and a former sales representative of Ortho-McNeil. (*Id.* ¶ 10.) West filed this qui tam action on behalf of the United States, California, Delaware, Florida, Hawaii, Massachusetts, Nevada, Tennessee, Texas, Virginia and the District of Columbia, who are the real parties in this action. (*Id.* ¶¶ 1, 8-9.)

I. Procedural History

West brought this qui tam action under the FCA and the similar laws of several states and the District of Columbia. (*Id.* ¶¶ 1, 8-9.) The FCA allows a private person, the relator, to bring a civil action on behalf of the United States Government when a false claim has been submitted to the Government. 37 U.S.C. §§ 3729, 3730(b). In a private action, the FCA first requires the relator to serve on the Government “[a] copy of the complaint and written disclosure of substantially all material evidence and information the person possesses.” 37 U.S.C. § 3730(b)(2). The complaint then remains under seal for 60 days during which time the government may elect to intervene and proceed with the action. *Id.* The United States, the states involved and the District of Columbia all have declined to intervene. The United States has submitted a Statement of Interest in which it advocates several points of law, but the United States does not take a position on whether West has pleaded his claim adequately under Rule 9(b).

In his First Amended Complaint, West claims that Defendants: (1) knowingly caused to be presented to the United States Government, and the governments of several states and the District of Columbia, false or fraudulent claims for payment; (2) knowingly made false statements to get false or fraudulent claims paid for by said governments; and (3) knowingly made false records or statements to conceal, avoid, or decrease obligations to pay money to said governments. (1st Am. Compl. ¶¶ 104-06, 113, 119-21, 127-29, 135-37, 142-44, 158-60, 166-68, 174-76, 182-84, 190-92, 198-200.) As factual support for these claims, West first alleges that Defendants utilized a wide array of kickbacks and unlawful remuneration to increase sales of its pharmaceutical drugs Levaquin and Ultram. (*Id.* ¶¶ 62-99.) Second, West alleges that Defendants marketed Levaquin and Ultram for non-FDA approved – “off-label” – uses. (*Id.* ¶¶ 100-01.)

The U.S. Judicial Panel on Multidistrict Litigation transferred West’s action to the District of Massachusetts, but separated and remanded to this Court the claims relating to off-label marketing. As such, remaining before this Court are the claims that Defendants: (1) knowingly caused to be presented to the United States Government and the governments of several states and the District of Columbia, via their off-label marketing practices, false or fraudulent claims for payment; and (2) knowingly made false statements, as part of their off-label marketing practices, to get false or fraudulent claims paid for by said governments.

II. Medicaid

The Medicaid program provides “medical assistance to individuals and families whose resources are insufficient to meet the costs of necessary medical services.” 42 U.S.C. § 1396. In order for a drug to be eligible for reimbursement through Medicaid, the drug’s manufacturer must enter into a rebate agreement with Medicaid that ensures that the price Medicaid pays is a

competitive one. 42 U.S.C. § 1396r-8(a)(1). Medicaid providers, such as pharmacies, pay drug manufacturers for prescription drugs and, in turn, submit claims to state Medicaid agencies for reimbursement. 42 U.S.C. § 1396a(a)(23), (a)(32). While claims are submitted to state Medicaid agencies, the federal government reimburses states for a substantial portion of the funds allotted. 42 U.S.C. § 1396. For this reason, claims submitted to state Medicaid agencies are considered claims presented to the federal government and may give rise to liability under the FCA. *U.S. ex rel. Tyson v. Amerigroup Illinois, Inc.*, 2005 WL 2667207 at *3 (N.D. Ill. 2005).

III. Off-Label Marketing and Medicaid

Under the Food, Drug, and Cosmetics Act (“FDCA”), 21 U.S.C. §§ 301-97, new pharmaceutical drugs cannot be introduced into interstate commerce unless the Food and Drug Administration (“FDA”) finds that the drug is safe and effective for each of its intended uses. 21 U.S.C. § 355(a), (d). Although doctors are allowed to prescribe a drug for off-label uses, drug manufacturers are prohibited from marketing or promoting a drug for a use that the FDA has not approved. 21 U.S.C. §§ 331(d), 355(a). Moreover, Medicaid generally reimburses providers only for “covered outpatient drugs.” 42 U.S.C. §§ 1396b(i)(10), 1396r-8(a)(3). “Covered drugs” do not include drugs “used for a medical indication which is not a medically accepted indication.” 42 U.S.C. § 1396r-8(k)(3). A medically accepted indication is one “approved under the Federal Food, Drug, and Cosmetic Act” or one included in certain, specified drug compendia. 42 U.S.C. § 1396r-8(k)(6); *see U.S. ex rel. Franklin v. Parke-Davis*, 147 F. Supp. 2d 39, 45 (D. Mass. 2001).

IV. West’s Allegations of Off-Label Marketing

West alleges that, with the knowledge and consent of marketing executives at Ortho-McNeil, sales representatives marketed two of Ortho-McNeil’s drugs, Levaquin and Ultram, for uses not yet

approved by the FDA. (1st Am. Compl. ¶ 100.) More specifically, Ortho-McNeil sales representatives: (1) instructed doctors that Levaquin should be used to treat prostatitis, a non-FDA approved use; (2) disseminated articles to doctors that promoted the use of Ultram for non-FDA approved conditions, including osteoarthritis and diabetic neuropathy; and (3) disseminated articles to doctors that recommended that Ultram be given at dosage levels not approved by the FDA. (*Id.* ¶ 101.) Placing these acts in terms of the FCA, West alleges that “each prescription that was written as a result of defendants’ illegal marketing practices . . . represents a false or fraudulent record or statement,” and claims for reimbursement for such prescriptions represent false or fraudulent claims for payment. (*Id.* ¶ 106.)

DISCUSSION

West’s action currently includes 12 counts: Count I, based on 31 U.S.C. § 3729(a)(1) and (a)(2) of the FCA, and Counts III through XIII, excluding VII, based on the similar laws of California, Delaware, Florida, Hawaii, Massachusetts, Nevada, Tennessee, Texas, Virginia, and the District of Columbia, respectively. Count II, brought under 31 U.S.C. § 3729(a)(7), did not involve alleged off-label marketing practices and thus was transferred to the District of Massachusetts. West voluntarily dismissed Count VII, his claim brought under the Illinois Whistleblower Reward and Protection Act.

The heightened pleading standard set forth in Rule 9(b) applies to actions brought under the FCA. *See U.S. ex rel. Garst v. Lockheed-Martin Corp.*, 328 F.3d 374, 376 (7th Cir. 2003) (“False Claims Act condemns fraud but not negligent errors or omissions”). Rule 9(b) requires that “in all averments of fraud . . . the circumstances constituting fraud . . . shall be stated with particularity.” These circumstances must include the “who, what, when, where, and how: the first paragraph of any

newspaper story.” *DiLeo v. Ernst & Young*, 901 F.2d 624, 627 (7th Cir. 1990). When a fraud scheme involves numerous transactions over time, a plaintiff need not plead specifics with respect to every instance of the fraud, but must plead at least representative examples of the fraud. *Bantsolas ex rel. U.S. v. Superior Air and Ground Ambulance Transport, Inc.*, 2004 WL 609793 at *4 (N.D. Ill. 2004); *Garst*, 328 F.3d at 376, 379.

I. West’s claims against Ortho-McNeil under 31 U.S.C. § 3729(a)(1), § 3729(a)(2) and similar laws of several states and the District of Columbia

A person violates the FCA when he “(1) knowingly presents, or *causes* to be presented, to an officer or employee of the United States Government . . . a false or fraudulent claim for payment or approval” or “(2) knowingly makes, uses, or *causes* to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government.” 31 U.S.C. § 3729(a)(1), (a)(2) (emphasis added). A person acts knowingly when he or she: “(1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information, and no proof or specific intent to defraud is required.” 37 U.S.C. § 3729(b). West does not contend that Defendants submitted false claims; instead, he alleges that Defendants knowingly *caused* such claims to be submitted. To meet Rule 9(b)’s heightened pleading for a claim under § 3729(a)(1), West must identify specific false claims for payment as well as (1) who submitted the false claim, (2) what the person submitted, (3) when he submitted the claim, (4) where he did so and (5) how he did so. *Garst*, 328 F.3d at 376. He also must plead how Defendants caused the claim to be submitted. *Id.* West’s § 3729(a)(2) claim requires him to identify particular false records or false statements that Defendants made in order to get the government to pay money. *U.S. ex rel. Lamers v. City of Green Bay*, 168 F.3d 1013, 1018

(7th Cir. 1999).

West alleges that Defendants caused false claims to be submitted by having Ortho-McNeil sales representatives instruct physicians that Levaquin should be used to treat prostatitis, a non-FDA approved use, and by having sales representatives disseminate articles to physicians promoting the use of Ultram for non-FDA approved conditions and at non-FDA approved dosage levels. West's allegations do not meet the heightened pleading standard set forth in Rule 9(b). *See, e.g., U.S. ex rel. Fowler v. Caremark RX, Inc.*, 2006 WL 2425331 at *7 (N.D. Ill. 2006). With respect to the sales representatives' allegedly false statements to doctors, West does not identify which sales representatives made the statements, when they made them, to which doctors they made them or how they communicated them. Nor does West identify which executives at Ortho-McNeil told sales representatives to make these false statements. At best, West describes the general subject of the alleged misrepresentations (Levaquin and Ultram should be used for non-FDA approved uses) and the general category of individuals (sales representatives) who made them. Such generalized allegations are insufficient where "they do not even hint at the identity of those who made the misrepresentations, the time misrepresentations were made, or the places at which the misrepresentations were made." *Uni*Quality, Inc. v. Infotronx, Inc.*, 974 F.2d 918, 923 (7th Cir. 1992).

Likewise, with respect to the sales representatives' alleged distribution of articles to doctors, West does not identify which sales representatives distributed the articles, what the articles or representatives stated that was false, when the sales representatives distributed them, to which doctors they distributed them or how they distributed them. While West need not plead every false statement made by Defendants or every false claim made, he does not set forth the circumstances of

any particular false statement or cite a single example of a false claim or a provider that made a false claim.

West tacitly concedes these deficiencies in his Complaint, but argues that the Rule 9(b) standard should be relaxed when the plaintiff does not have access to all the facts necessary to detail his claim. Absent rare circumstances, however, relaxing the Rule 9(b) pleading standard would undermine the purposes of fraud pleading generally and the FCA specifically. *See Karvelas v. Melrose-Wakefield Hospital*, 360 F.3d 220, 230-231 (1st Cir. 2004) (refusing to relax Rule 9(b) pleading standard where evidence of FCA claim was allegedly unavailable to plaintiff). The FCA, for instance, prohibits qui tam actions based upon publicly disclosed information unless the relator is the “original source” of that information. 31 U.S.C. § 3730(e)(4)(B). An “original source” is a person “who has direct and independent knowledge of the information on which the allegations are based.” *Id.* The private enforcement provisions of the FCA allow for whistleblower-type actions that enhance the Government’s enforcement of the statute.² *See Fanslow v. Chicago Mfg. Center, Inc.*, 384 F.3d 469, 478-79 (7th Cir. 2004). If a relator cannot plead with particularity alleged violations of the FCA, he stands in no better position to assist the Government than any other citizen.

Requiring a relator to plead with particularity also comports with the FCA’s requirement that the complaint be filed under seal for 60 days while the Government decides whether to intervene. Unless a relator makes particular allegations prior to discovery, the Government would be forced to decide “whether or not to intervene absent complete information about the relator’s cause of action.” *Karvelas*, 360 F.3d at 230-231 (quoting Boese, *Civil False Claims and Qui Tam Actions* § 4.04[C]).

² Consistent with this design, the FCA provides specific protections against retaliatory acts by an employer. *See* 31 U.S.C. § 3730(h); *U.S. ex rel. Tyson v. Amerigroup Illinois, Inc.*, 2006 WL 4586279 at *4 (N.D. Ill. 2006) (“The Illinois Whistleblower Act is virtually identical to the FCA”).

If West has direct knowledge that sales representatives caused physicians to submit claims based on prescriptions of Levaquin and Ultram for non-FDA approved uses, he must allege specifically the “who, what, when, where, and how” of the false statements and the false claims. Without concrete examples of false statements and false claims, it seems as if West has filed suit based upon his suspicion that Defendants engaged in unlawful conduct with the hope that discovery will unearth some specific FCA violation. *See U.S. ex rel. Robinson v. Northrop Corp.*, 149 F.R.D. 142, 144 (N.D. Ill. 1993) (FCA Complaint may not be “filed as a pretext to uncover unknown wrongs”). Rule 9(b) does not tolerate such suits. *See Vicom, Inc. v. Harbridge Merchant Services, Inc.*, 20 F.3d 771, 777 (7th Cir. 1994) (Rule 9(b) “serve[s] three main purposes: (1) protecting a defendant’s reputation from harm; (2) minimizing “strike suits” and “fishing expeditions”; and (3) providing notice of the claim to the adverse party”). Accordingly, West has not pleaded with the required particularity the circumstances of his § 3729(a)(1) and (a)(2) claims. For this reason, the Court will not address whether any additional facts that West may allege would state a claim under Rule 12(b)(6).

II. West’s claims against Johnson & Johnson

When considering a motion under Rule 12(b)(6), a court must take as true all facts alleged in the complaint and construe all reasonable inferences in favor of the plaintiff. *See Murphy v. Walker*, 51 F.3d 714, 717 (7th Cir. 1995). The plaintiff need not allege all of the facts involved in the claim. *See Sanjuan v. American Bd. of Psychiatry and Neurology, Inc.*, 40 F.3d 247, 251 (7th Cir. 1994). The claim though must be supported with enough facts, taken as true, that plausibly suggest that the plaintiff is entitled to relief. *See Bell Atlantic Corp. v. Twombly*, 127 S. Ct. 1955, 1965 (2007).

Johnson and Johnson is Ortho-McNeil's corporate parent. West has not set forth facts that plausibly suggest a cause of action against Johnson & Johnson. A corporate parent is not automatically liable for torts committed by its subsidiary. *See IDS Life Ins. Co. v. SunAmerica Life Ins. Co.*, 136 F.3d 537, 540 (7th Cir. 1998). West implies that Johnson & Johnson might be liable under a "piercing the corporate veil" theory; however, he has pleaded no facts to support such a theory. *See Int'l. Financial Services Corp. v. Chromas Technologies Canada, Inc.*, 356 F.3d 731, 736-37 (7th Cir. 2004). Therefore, the claims against Johnson & Johnson are dismissed.

CONCLUSION AND ORDER

West's claims against Ortho-McNeil are dismissed pursuant to Rule 9(b) because he has failed to plead fraud with particularity. West's claims against Johnson & Johnson are dismissed because he has not pleaded facts that plausibly suggest a cause of action against Johnson & Johnson. Dismissal of the claims based upon West's allegations is without prejudice to the United States. Wherefore, Defendants' Motion to Dismiss is granted. West is granted 30 days from the date of this order to file an amended complaint consistent with this opinion.

So ordered.



Virginia M. Kendall
United States District Judge
Northern District of Illinois

Date: July 20, 2007